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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,320

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Yoshiko Takayama

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EXAMINER

HUANG, GIGI GEORGIANA

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

03/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,320	Applicant(s) TAKAYAMA ET AL.	
	Examiner GIGI HUANG	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-16 is/are pending in the application.
- 4a) Of the above claim(s) 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/13/2006, 4/13/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on November 20, 2008 is acknowledged.

Claims 14-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Status of Application

2. Applicant has elected Group I in response to restriction requirement and for the examination.

Due to restriction, based on election of Group I, claims 14-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Claim 13 is present for examination at this time.

Information Disclosure Statement

4. The information disclosure statement filed 1/13/2006 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because several references do not have translations. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing

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the statement, including all certification requirements for statements under 37 CFR

1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The term "Rho protein inhibitor" is not defined and it does not address which combination of receptors are target, the amount of binding desired for the receptors, nor the degree of inhibition, and the compounds that would accomplish this other than fasudil hydrochloride, etacrynic acid and 4-[2-(2,3,4,5,6-pentafluorophenyl)acryloyl]cinnamic acid, 2-chloro-6,7-dimethoxy-N-[5-1H-indazolyl]quinazoline-4-amine, N-(1-benzyl-4-piperidinyl)-1H-indazole-5-amine dihydrochloride monohydrate, and C3 enzyme which is disclosed in the specification.

The term "Rho protein inhibitor" is not adequately described as it is defined by a functional characteristic where it is defined by what it *does* and not what it *is*. Second, it does not describe adequately the degree of access, binding, or activity to the receptor

to ascertain what compounds would fulfill the description. As a result, the fact pattern indicates that the artisan was not in possession of the claimed method of use.

There is also no specific structure/function relationship taught in the reference to drawn from as the specific compounds disclosed have different cores with no specific relationship to the function recited in the claims. The claims with the term also encompass compounds yet to be found whereby Applicant would not be in possession of all the compounds embraced by the term. McKerracher et al. (U.S. Pat. Pub. 2008/0233098) teaches screening assays to identify Rho antagonists (inhibitors) which are after the filing date of the instant application (Paragraph 16-23, 44-50). Thereby, while having written description fasudil hydrochloride, etacrynic acid and 4-[2-(2,3,4,5,6-pentafluorophenyl)acryloyl]cinnamic acid, 2-chloro-6,7-dimethoxy-N-[5-1H-indazolyl]quinazoline-4-amine, N-(1-benzyl-4-piperidiny)-1H-indazole-5-amine dihydrochloride monohydrate, and C3 enzyme, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hellberg et al. (WO 03/020281) in view of Lehmann et al (Inactivation of Rho Signaling Pathway Promotes CNS Axon Regeneration).

Hellberg et al. teaches the use of compounds that promote neuron regeneration or neurite outgrowth for the treatment of conditions such as dry eye and other conditions related to corneal nerve damage (e.g. corneal sensitivity after LASIK). The compounds are neurotrophic and are used promote neurite outgrowth or regenerate severed neurons, examples include neotrofin, idebenone, and clenbuternol (see full document, specifically Abstract, Page 4 line 16-Page 5 line 25, Page 6 line 12-23, Claim 1-4, 7-10, 13-16).

Hellberg et al. do not expressly teach the use of Rho inhibitors.

Lehmann et al. teaches that Rho inhibition fostered regeneration of neurons and yielded extended neurites. Lehmann teaches that in vitro test showed that C3 affected the growth of neurites from retinal cells and in vivo Lehmann tested optic nerves with C3 transferease (C3 enzyme) showing that the transected axons fostered extension and regeneration.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize a Rho inhibitor that promotes neuron regeneration or neurite outgrowth for corneal injury, as suggested by Lehmann, and produce the instant invention. It would be obvious for one of skill in the art to use another neurite promoter such as a Rho inhibitor (e.g. C3 in Lehmann) for corneal injury as Hellberg et al. teaches the use of compounds that promote neuron regeneration or neurite

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outgrowth for corneal disorders and it is obvious to use a known neurite/neuron promoter for a known purpose for neurite/neuron promoters for a specific treatment.

One of ordinary skill in the art would have been motivated to do this because it is desirable to use a known compound such as C3 (Rho inhibitor) with known properties for promoting axon extension and regeneration in vivo in the eye, to be used for a known purpose (neurite/neuron promoters for corneal disorders) which utilizes compounds that promotes neuron regeneration or neurite outgrowth, as it is desirable to have different compounds useful for the same purpose and to have new methods of treatment for a known compound which allows for new sales.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

9. Claim 13 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 19-27 of U.S. Patent No. 7485654. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims anticipate the broader instant claim.

Conclusion

10. Claim 13 is rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612

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